DEPARTMENT OF HEALTH AND HUMAN SERVICES

J5048d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 2, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-06

Jay L. De Jong, Owner
Rhody Dairy
9056 Telegraph Road
Sumas, Washington 98295

WARNING LETTER

Dear Mr. De Jong:

On June 8, 9, and 16, 2004, our investigator inspected your dairy farm located at the 9056 Telegraph Road, Sumas, Washington. That inspection confirmed that you offered a dairy cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On December 8, 2003, you sold a dairy cow identified with back tag No. [redacted] and further identified as USDA-FSIS lab report # 443924, for slaughter as human food to [redacted], who then sold the dairy cow to [redacted] U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of flunixin at 0.21 parts per million (ppm) (or 210 parts per billion (ppb)) in the liver. At the time you offered this cow for sale, flunixin had not yet been approved for use in lactating dairy cattle. The presence of flunixin in the liver of this dairy cow indicated that you treated this cow with flunixin and that this use did not conform to the then-approved use, or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act. In addition, the presence of flunixin residues caused the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act because it contained a new animal drug that is unsafe within the meaning of Section 512 of the Act.

Flunixin was approved for use in lactating dairy cows as of August 19, 2004. (See 69 Fed. Reg. 60308 (Oct. 8, 2004), copy enclosed). The established tolerance of flunixin in cattle is 0.125 ppb in liver. It is important to note that even if flunixin had been approved for use in lactating dairy

cattle at the time you offered this cow for sale, the residue of flunixin in this cow (0.21 ppm or 210 ppb) would have exceeded the tolerance set for flunixin in cattle (0.125 ppm or 125 ppb).

Our investigation also found that you hold animals under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example:

- You lack an adequate system for determining the medication status of animals you offer for slaughter;
- you lack an adequate system to assure that medicated animals are withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs in edible tissues;
- and you lack an adequate system to ensure that drugs are used in a manner not contrary to the directions contained in their labeling.

Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

It is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act. Similarly, it is not necessary for you to personally ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of an animal drug that had been shipped in interstate commerce is sufficient to hold you responsible.

The above is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for ensuring that your overall operations and the food you distribute are in compliance with the law, including the extralabel use regulations promulgated under the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Ms. Althar at (425) 483-4940.

Sincerely,

/Kristy D. Nuss
for Charles M. Breen
District Director

Enclosures: 21 CFR 530 and 522.970
69 Fed. Reg. 60308 (Oct. 8, 2004)

cc: (w/copy of FDA-483):
Lael Alberg, DVM
U.S. Department of Agriculture
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501